REMARKS

In the Office Action dated September 26, 2003, Claims 1-28 are pending in the present application and have been subjected to restriction by the Examiner under 35 U.S.C. §121 as follows:

Group I. Claims 1-7, 10-16 and 19-25, drawn to a method of treating an immune-mediated disease, classified in Class 514, subclass 885.

Group II. Claims 8-9, 17-18 and 26-28, drawn to immunoglobulin compositions comprising Cohn Fractions II+III, II, or III, classified in Class 424, subclass 130.1.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents two separate and distinct groups. The Examiner admits that Group II and Group I are related as product and process of use. The Examiner alleges that the method of Group I can be practiced with other non-immunoglobulin compositions and the immunoglobulin composition of Group II can be used in a materially different process of using the composition, e.g., to establish background levels of antibody binding in antigen-detection assays such as for detection of increases in serum specificities for a particular antigen of diseases. The Examiner further alleges that the present invention contains claims directed to the following species of Group I and II, wherein the Cohn Fraction is:

A) Fraction II+III
B) Fraction II alone, or
C) Fraction III alone.

The Examiner requires that Applicants elect a single disclosed species for prosecution on the merits. As indicated, and in order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect to prosecute, with traverse, the subject matter of Group II, Claims 8-9, 17-18 and 26-28, directed to immunoglobulin compositions comprising Cohn Fraction II+III. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application. Accordingly, Applicants submit that Claims 8-9 and 28 are readable on the elected species.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. In the first instance, Applicants observe that the Examiner alleges that the method of Group I can be practiced with other non-immunoglobulin compositions, such as prednisone. Applicants note that prednisone is a synthetic derivative of glucocortoid cortisone which is a steroid given orally for inflammation. In this regard, Applicants respectfully direct the Examiner's attention to the

fact that a principal feature of the present invention is to overcome the significant risks and side effects of using steroids in a method for treating an immune-mediated diseases. See specification at page 5, line 25 to page 6, line 2 and page 7, line 18 to page 8, line 2, for example. Thus, the present invention provides a method for treating an immune-mediated diseases with a significant clinical improvement of the condition of the patient, which cannot be achieved by "other non-immunoglobulin compositions" as the Examiner contends. Groups I-II are related aspects of the present invention. For example, Group II is the product employed in the processes of Group I, i.e., treating an immune-mediated diseases with a significant clinical improvement of the condition of the patient.

Accordingly, Groups I-II are very clearly interrelated and interdependent, not "independent and distinct."

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would

require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of Applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

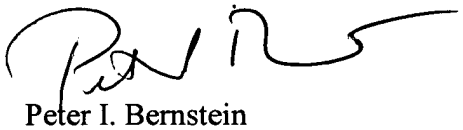
Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



Peter I. Bernstein
Registration No. 43,497

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

PIB/ZY:ab